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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,365	04/13/2004	Gavril Pasternak	62069DIV2(51590)	4859
21874	7590	11/30/2005	EXAMINER	
EDWARDS & ANGELL, LLP			MITCHELL, GREGORY W	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	

1617

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,365

Applicant(s)

PASTERNAK ET AL.

Examiner

Gregory W. Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 16-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04/13/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed September 12, 2005. Claim 21 has been amended. Claims 1-35 are pending. Claims 1-10 and 14-15 are withdrawn from consideration. Claims 11-13 and 16-35 are examined herein.

Election/Restrictions

Applicant's election with traverse of Group III, directed to a method of providing topical analgesia in the reply filed on September 12, 2005 is acknowledged. The traversal is on the ground(s) that the search for Group III methods would inevitably encompass the Group I compositions. This is not found persuasive because, for example, administration of the compositions claimed could occur via a different mode than topical administration. It is noted that while the searches may be overlapping, there is no reason to believe that the searches would be co-extensive. Furthermore, the search of the compositions will not be sufficient to be a complete search for the methods because Examiner must also search the art for enablement considerations. Applicant's election of morphine as a species of opioid and butamben as a species of local anesthetic are acknowledged.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-10 and 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

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generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 12, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-20, 22-26 and 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-20, 22-26 and 28-32 are indefinite because each claim recites a limitation whereby the dose of a given ingredient is "administered in a dosage of about [x]% to about [y]%." It is unclear how a dose amount can be a percentage. For examination purposes, Examiner interprets such percentages as being directed to the percentage active in the composition administered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, 16-26 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elkhoury et al. (USPN 5589480) in view of Ptchelintsev et al. (USPN 5834513).

Elkhoury et al. teaches the topical administration of an opioid drug, such as morphine, for producing analgesic effect in a localized peripheral area without transdermal migration of the opioid drug into the blood stream (Abstract; col. 2, lines 51-60; col. 4, lines 46-57). Administration to the skin is taught (Figures 1 and 2). Elkhoury et al. does not teach the claimed concentrations or the inclusion of butamben.

Ptchelintsev et al. teaches that butamben is a topical analgesic (col. 8, lines 1-2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine morphine and butamben in a composition for providing topical analgesic effect because Elkhoury et al. teaches the morphine composition disclosed therein as a composition for achieving topical analgesia and Ptchelintsev et al. teaches butamben as known in the art as a topical analgesic. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

It is noted that Elkhoury et al. teaches the compositions disclosed therein for achieving peripheral analgesia generally and that Ptchelintsev et al. teaches butamben, generally, as a topical analgesic. Accordingly, it would have been obvious to one of

ordinary skill in the art to arrive at the concentrations claimed because "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elkhoury et al. and Ptchelintsev et al. as applied to claims 11-13, 16-26 and 33 above, and further in view of Mayer et al. (USPN 5840731).

Elkhoury et al. and Ptchelintsev et al. apply as disclosed above. The reference lack a teaching of an NMDA receptor antagonist.

Mayer et al. teaches that the analgesic effectiveness of a combination drug composition comprising at least one analgesic is significantly enhanced by the addition of an NMDA receptor antagonist (Abstract). Mayer et al. teaches compositions comprising a first analgesic, a second component, and an analgesia-enhancing amount of an NMDA receptor antagonist and methods of treatment for alleviating pain by the administration thereof (col. 1, lines 6-27; col. 2, lines 30-col. 3, line 5; col. 4, line 67-col. 5, line 13). Analgesics are taught to be selected from fentanyl, morphine, etc. (col. 3, lines 57-65). NMDA receptor antagonists are taught to be selected from ketamine, etc. (col. 4, lines 33-50).

It would have been obvious to one of ordinary skill in the art to administer a topical composition comprising the morphine, butamen and an NMDA receptor antagonist because (1) Elkhoury et al. and Ptchelintsev et al. teach the morphine and

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butamen, respectively, as analgesics suitable for topical administration; and (2) Mayer et al. teaches that the addition of an NMDA receptor antagonist (e.g. ketamine) to an analgesic composition is known in the art to significantly enhance the analgesia provided thereby. One would have been motivated to prepare and utilize such a composition because of an expectation of success in providing a topical composition suitable for peripheral relief with significantly enhanced analgesic effects, as taught by Mayer et al.

It is noted that Mayer et al. teaches the NMDA receptor antagonists disclosed therein for achieving improved analgesia generally. Accordingly, it would have been obvious to one of ordinary skill in the art to arrive at the concentrations claimed because "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elkhoury et al. and Ptchelintsev et al. as applied to claims 11-13, 16-26 and 33 above, and further in view of Soo (USPN 5028595).

Elkhoury et al. and Ptchelintsev et al. apply as disclosed above. Furthermore, it is noted that Elkhoury et al. specifically teaches the treatment of painful conditions associated with inflammation (col. 2, lines 51-60).

Soo teaches that morphine is known in the art for the treatment of peripheral neuropathy (col. 62-66).

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat the claimed conditions because (1) Elkhoury et al. teaches that morphine is known in the art to treat painful inflammatory disorders in general; and (2) Soo teaches that morphine is known in the art to treat peripheral neuropathy. One would have been motivated to treat the claimed conditions with the morphine compositions of the invention because of an expectation of success in treating the pain associated with the conditions.

Conclusion

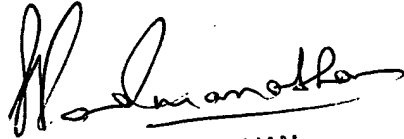
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm



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